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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/594,348 | 08/15/2007 | Reynold Homan | PC25819A | 9390 |
| 28523 | 7590 | 04/07/2008 | EXAMINER | |
| PFIZER INC. PATENT DEPARTMENT, MS8260-1611 EASTERN POINT ROAD GROTON, CT 06340 | | | WEDDINGTON, KEVIN E | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1614 | |
| | | | NOTIFICATION DATE | DELIVERY MODE |
| | | | 04/07/2008 | ELECTRONIC |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

~IPGSGro@pfizer.com

| | | | |
|------------------------------|--|-------------------------------------|--|
| Office Action Summary | Application No. 10/594,348 | Applicant(s) HOMAN ET AL. | |
| | Examiner Kevin E. Weddington | Art Unit 1614 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 August 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 10 and 16-41 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 10 and 16-41 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 September 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicants' drawings filed September 26, 2006; and the preliminary amendment filed August 15, 2007 have been received and entered.

Due to the complex nature of the claims, no request for an oral election is being made. Please see MPEP 812.01.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 10 and 32-41 are drawn to a pharmaceutical composition and a kit containing the pharmaceutical composition comprising a) a compound that is a serine palmitoyltransferase inhibitor; and b) a second compound useful for the treatment of atherosclerosis or dyslipidemia, classified in class 514, subclass 183.
- II. Claims 16 and 31 are drawn to a method of lowering plasma lipids comprising administering a therapeutically effective amount of a serine palmitoyltransferase inhibitor to a mammal in need thereof, classified in class 514, subclass 183.
- II. Claims 17 and 31 are drawn to a method for elevating high density lipoprotein particles comprising administering a therapeutically effective amount of a serine palmitoyltransferase inhibitor to a mammal in need thereof, classified in class 514, subclass 183.
- IV. Claims 18 and 31 are drawn to a method for lowering very low density lipoprotein particles and low density lipoprotein particles comprising

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administering a therapeutically effective amount of a serine palmitoyltransferase inhibitor to a mammal in need thereof, classified in class 514, subclass 183.

- V. Claims 19 and 31 are drawn to a method for lowering plasma triglycerides particles comprising administering a therapeutically effective amount of a serine palmitoyltransferase inhibitor to a mammal in need thereof, classified in class 514, subclass 183.
- VI. Claims 20 and 31 are drawn to a method for lowering serum levels of total cholesterol comprising administering a therapeutically effective amount of a serine palmitoyltransferase inhibitor to a mammal in need thereof, classified in class 514, subclass 183.
- VII. Claims 21 and 31 are drawn to a method for improving plasma lipid profile comprising administering a therapeutically effective amount of a serine palmitoyltransferase inhibitor to a mammal in need thereof, classified in class 514, subclass 183.
- VIII. Claims 22 and 31 are drawn to a method for inhibiting plaque formation comprising administering a therapeutically effective amount of a serine palmitoyltransferase inhibitor to a mammal in need thereof, classified in class 514, subclass 183.
- IX. Claims 23 and 31 are drawn to a method of reducing the size of plaque comprising administering a therapeutically effective amount of a serine

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palmitoyltransferase inhibitor to a mammal in need thereof, classified in class 514, subclass 183.

- X. Claims 24 and 31 are drawn to a method of reducing the size of an atherosclerotic lesion comprising administering a therapeutically effective amount of a serine palmitoyltransferase inhibitor to a mammal in need thereof, classified in class 514, subclass 183.
- XI. Claims 25 and 31 are drawn to a method of reducing the size of a macrophage foam cell comprising administering a therapeutically effective amount of a serine palmitoyltransferase inhibitor to a mammal in need thereof, classified in class 514, subclass 183.
- XII. Claims 26 and 31 are drawn to a method for preventing plaque rupture comprising administering a therapeutically effective amount of a serine palmitoyltransferase inhibitor to a mammal in need thereof, classified in class 514, subclass 183.
- XIII. Claims 27 and 31 are drawn to a method for treating dyslipidemia which comprises administering a therapeutically effective amount of a serine palmitoyltransferase inhibitor to a mammal in need thereof, classified in class 514, subclass 183.
- XIV. Claims 28 and 31 are drawn to a method for treating atherosclerosis which comprises administering a therapeutically effective amount of a serine palmitoyltransferase inhibitor to a mammal in need thereof, classified in class 514, subclass 183.

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- XV. Claims 29 and 31 are drawn to a method for treating diabetes which comprises administering a therapeutically effective amount of a serine palmitoyltransferase inhibitor to a mammal in need thereof, classified in class 514, subclass 183.
- XVI. Claims 30 and 31 are drawn to a method for treating metabolic syndrome which comprises administering a therapeutically effective amount of a serine palmitoyltransferase inhibitor to a mammal in need thereof, classified in class 514, subclass 183.

The inventions are distinct, each from the other because of the following reasons:

Inventions II and I are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the product as claimed can be used in a materially different process of using that product.

The sixteen inventions have separate statuses in the art as shown by their different and separate subject matter for inventive effort. Further, a reference, which anticipates any one of the above inventions, would neither anticipate nor make obvious of the other inventions. Each such invention is capable of supporting its own patent. For these reasons, the restriction requirement is proper.

To be complete, applicants' response must include a provisional election even though the requirement may be traverse.

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The applicants are required to elect a single invention for examination purposes.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where

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the restriction requirement is withdrawn by the examiner before the patent issues.

See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kevin E. Weddington whose telephone number is (571)272-0587. The examiner can normally be reached on 12:30 pm-9:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on (571)272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Kevin E. Weddington
Primary Examiner
Art Unit 1614

/Kevin E. Weddington/
Primary Examiner, Art Unit 1614

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